



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/076,956	05/13/1998	LUDMILLA BARANOVA	GEN-T104D1	5479

25871 7590 12/02/2003

SWANSON & BRATSCHUN L.L.C.
1745 SHEA CENTER DRIVE
SUITE 330
HIGHLANDS RANCH, CO 80129

EXAMINER

CRANE, LAWRENCE E

ART UNIT	PAPER NUMBER
----------	--------------

1623

DATE MAILED: 12/02/2003

57

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/076,956	Applicant(s) Baranova et al.	
	Examiner L. E. Crane	Group Art Unit 1623	

- THE MAILING DATE of this communication appears on the cover sheet beneath the correspondence address -

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE **--3--** MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be filed after six months from the date of this communication.
- If the prior for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 USC §133).

Status

- ☒ Responsive to communication(s) filed on **-11/08/03 (amdt K)-**.
- ☒ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claims **---110-114---** are pending in the application. Claims **-[]-** have been cancelled. Of the above claim(s) **---[]---** is/are withdrawn from consideration.
- ☐ Claim(s) **---[]---** is/are allowed.
- ☒ Claims **---110-114---** are rejected.
- ☐ Claim(s) **---[]---** is/are objected to.
- ☐ Claim(s) **---[]---** are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on **-[]-** is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on **-[]-** is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119(a)-(d)

- ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119 (a)-(d).
- ☒ All ☐ Some ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) **-[]-**.
- ☒ received in the national stage application from the International Bureau (PCT Rule 17.2(a)).
- * Certified copies not received: **-[]-**.

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). **---[]---**
- ☒ Notice of Reference(s) Cited, PTO-892 (Update)
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413, P.N. ☐.
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other: **-[]-**.

U.S. Patent Trademark Office

Office Action Summary

PTO-326 (Rev. 06/19/01)

S. N. 09/076,956

Paper No. **51**

Copy for ☒ FILE ☐ APPLICANT

Art Unit 1623

No claims have been cancelled, claims **110-113** have been amended, pages 20 and 21 of the disclosure have been replaced by substitute pages, and new claim **114** has been entered as per the amendment of September 8, 2003. No additional Information Disclosure
5 Statements (IDSs) have been received.

Claims **110-114** remain in the case.

The disclosure is objected to because of the following informalities:

The replacement pages submitted by applicant are noted and represent a considerable improvement. However, the ribose rings
10 presented in each of the structures are representative of L-ribosyl, not D-ribosyl as found elsewhere in the disclosure. Resubmission of the reaction schemes altered to show the D-configuration is respectfully requested.

In addition, while reviewing the disclosure examiner noted that the
15 upper right hand structure at the bottom of page 14 is missing the "B" substituent and the structure at the lower right hand portion of the same scheme appears to show a "C" where an "O" should be in the expected cyclic phosphate diester product.

Appropriate correction is required.

20 Claims **110-114** are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Art Unit 1623

In claim **110** at lines 8-9 (step b)), the noted step the basis for this rejection because the term "opening the epoxide ring ... structure (I)" fails to list the reagents doing the opening and therefore is entirely functional.

5 Applicant's arguments with respect to claims **110-113** have been considered but are deemed to be moot in view of the new grounds of rejection. The new grounds of rejection was necessitated by applicant's amendments changing the instant claims from compound to method of making claims.

10 Claims **110-114** are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one of ordinary skill in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

15 The fundamental issue here is whether practicing the full scope of the instant invention is possible without undue experimentation. As provided for in *In re Wands* (858 F.2d 731, 737; 8 USPQ 2d 1400, 1404 (Fed Cir. 1988) the minimum factors to be considered in determination of whether a conclusion of "undue experimentation" is appropriate are
20 as follows:

A. The breadth of the claims extends to modified supports wherein the attached organic residue with a terminal epoxide or hydroxy/"Nu" functions is defined to be entirely organic (contains C & H only) except for the polymeric support.

25 B. The nature of the invention is a process for making oligonucleotides wherein the support including attached phosphate can

Art Unit 1623

be removed completely once the oligonucleotide has been synthesized by contacting the solid-support/oligonucleotide conjugate with a basic or nucleophilic reagent.

5 C. The state of the prior art is well defined, particularly by the **Webb et al. '774** reference (PTO-892 ref. **B**).

D. The level of one or ordinary skill is moderate, the only requirement being knowledge of how to conduct an organic chemical synthesis reaction, a level of knowledge typically found to be within the purview of any Bachelors or Masters degree holder.

10 E. The level of predictability in the art is low because the prior art does not describe how to make the all-organic-linker equipped solid supports which are required starting materials herein.

15 F. The amount of direction provided by the inventor is non-existent because there is no example in the disclosure or in the prior art cited therein wherein the preparation of an all-organic-linked epoxide or related solid support conjugate is disclosed.

G. The existence of working examples as suggested above, is limited to examples which do not include an all-organic-linked epoxide or related solid support conjugate.

20 H. The quantity of experimentation needed to make or use the invention based on the content of the disclosure is deemed to be undue because of the lack of guidance from any one of i) the cited prior art, ii) the disclosure or iii) examples within the disclosure of how to make or use an all-organic-linked epoxide or related solid support conjugate.

Art Unit 1623

Examiner further notes that if applicant amends to avoid this rejection, the anticipation rejection in the previous Office action (Webb et al. '774) may apply because the subject matter disclosed therein appears to anticipate some of the examples provided in the instant disclosure.

Applicant's arguments with respect to claims 110-113 have been considered but are deemed to be moot in view of the new grounds of rejection. The new grounds of rejection was necessitated by applicant's amendments changing the instant claims from compound to method of making claims.

Claims 110 and 113 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 110 at lines 17-18, the term "opening the epoxide ring" is incomplete because the process step (step b)) fails to include a list of reagents or reactants which are the chemical actors which lead to the ring-opened product.

In claim 113 at line 6, the term (II'b) is not included as a structure in the previous listing of structures and therefore renders the claim incomplete or incorrect. Did applicant intend to refer to variable "(I'b)" and the associated structure found at line 4?

Applicant's arguments with respect to claims 110-113 have been considered but are deemed to be moot in view of the new grounds of rejection. The new grounds of rejection was necessitated by applicant's

Art Unit 1623

amendments changing the instant claims from compound to method of making claims.

Applicant's amendments necessitated the new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP 706.07(a).

5 Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. §1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS
10 OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. §1.136(a) WILL BE
15 CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Papers related to this application may be submitted to Group 1600 via facsimile transmission(FAX). The transmission of such papers must
20 conform with the notice published in the Official Gazette (1096 OG 30, November 15, 1989). The telephone numbers for the FAX machines operated by Group 1600 are (703) 308-4556 and 703-305-3592.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner L. E.
25 Crane whose telephone number is 703-308-4639. The examiner can normally be reached between 9:30 AM and 5:00 PM, Monday through Friday.

Serial No. **09/076,956**

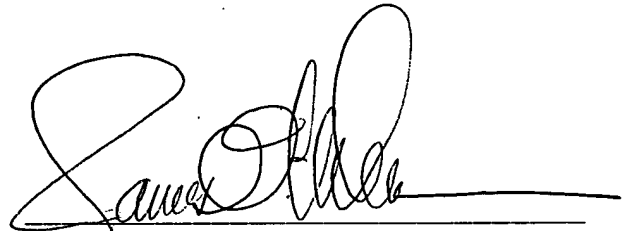
7

Art Unit 1623

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson, can be reached at (703)-308-4624.

5 Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is **703-308-1235**.

LECrane:lec
11/20/03


James O. Wilson
Supervisory Patent Examiner
Technology Center 1600

10